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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,446	11/28/2005	Ulf Gyllensten	25401-38	8097

24256 7590 10/22/2007

DINSMORE & SHOHL, LLP
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
10/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,446	GYLLENSTEN ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/05; 11/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.
Raw Sequence Listing have been entered.
Submitted Information Disclosure Statement (I.D.S) is noted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The scope of claim 1 reads entirely on mental processes. It appears that the entire "estimation of the risk" for papillomavirus as currently presented depends on mental process.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: amplification step, how is the amplification determined, the calculation parameters to establish a standard curve wherein estimating the risk can be

determined, the estimation of combined risk, the odds ratios are missing, etc.... This affects dependent claims 2-20.

Claim 1 is vague, indefinite, and rather confusing. The steps are rather confusing for not practically setting out the claimed method. For example, step (i) broadly refers to "identification of HPV", however, no steps are set to disclose how this is suppose to be performed. The specification talks about utilization of PCR method, but the scope of the claim is rather broad. In addition, no calculating amount method has been disclosed. How is the risk is estimated?

Claim 10 recites the limitation "risk estimation values.....predictive values (PPV)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "risk estimation values.....predictive values (PPV)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "risk estimation values.....predictive values (PPV)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

In addition, claims 10-12 are further indefinite for recitation of "odds ratio (OR), relative risk (RR), and/or positive predictive values (PPV)", none of these parameters have been defined. Claims have been interpreted in light of the disclosure and since the disclosure does not set forth adequate teaching these claims are deemed indefinite.

Claim 13 recites the limitation "wherein the human being.....in situ (CIS)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. This affects dependent claim(s).

Claim 14 recites the limitation "wherein the human being.....in situ (CIS)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. This affects dependent claim(s).

Claim 15 recites the limitation "wherein the human being.....in situ (CIS)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. This affects dependent claim(s).

Claim 16 recites the limitation "wherein the human being.....in situ (CIS)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. This affects dependent claim(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The field of viral detection in general, and risk assessment of viral particles detection to a cause of cancer in particular, is rather unpredictable. Absent clear teaching by the disclosure and clear setting of the steps in the

claims undue experimentation would be required for one of ordinary skill in the art to practice the claimed invention. The claimed invention does not set forth the parameters that are required to determine the risk posed by a particular HPV sample or types, and ultimately no viable estimation can be determined form the presently drafted claims. Applicants' own disclosure is the tantamount to the unpredictability of the field. Applicants on page 15, lines 31 to 33, and page 16, lines 1-7, talk about the importance of OR curves and their ability to be able to accurately estimate the risk. Disclosure further indicates that by merely counting the total number of HPV copies the result is a "dramatic" underestimate of the risk. Yet, the claims as drafted, especially main claim 1, do not reflect such teaching.

By simply following the steps of claim 1 no estimation of risk to HPV development can be determined. This means the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the claimed invention without undue experimentation. See In re Wright, 999 F.2d 1557,1562, 27USPQ2d 1510, 1513 (Fed. Cir. 1993).

Additionally regarding an unpredictable field, the current disclosure does not constitute an adequate disclosure. See See Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk, 108 F.3d 1361, 42 USPQ2d 1001 (Fed.Cir. 1997). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for a method of estimating a risk of carcinoma in a human being exposed to human papillomavirus infection in general, and cervical carcinoma in particular. This means that the

disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Josefsson et al (Journal of Clinical Microbiology, Mar. 1999, Vol. 37, No. 3, pages 490-496).

The teaching of the above cited art meets the broad limitations of the claimed invention. The current Claim 1 recites identification of "one or more" HPV in a sample. Josefesson et al also taught a method of detection and quantification of human papillomavirus for a single or one Human papillomavirus utilizing PCR (see the abstract). Following the teaching of above cited art would lead to "estimation of risk" in a sample from human being. Additionally, under inherency doctrine where the claimed and prior art are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a

prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

10/19/2007

ALI R. SALIMI
PRIMARY EXAMINER